DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 - 2004

Master & Frank Enterprises Company Limited
C/O Ms. Jennifer Reich
Harvest Consulting Corporation
3892 South America West Trail
Flaggstaff, Arizona 86001

Re: K020393
Trade/Device Name: Master & Frank Surgical Drapes (Sterile)
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: January 30, 2004
Received: February 17, 2004

Dear Ms. Reich:

This letter corrects our substantially equivalent letter of April 19, 2002, regarding the incorrect product code.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

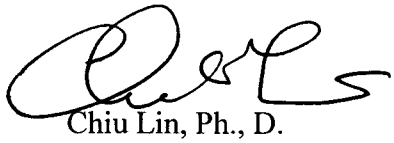
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Acts requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph., D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 510(K) SUMMARY

MAY 0 3 2002 K020393

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: **Master & Frank Enterprise Co., Ltd.**
   Address: 15F-1, No. 57, Sec. 2, Tun Hwa S. Rd. Taipei, Taiwan, R.O.C.
   Phone: 886-2-2325-5066
   Fax: 886-2-2702-6577
   Contact: Mr. Frank Wu (General Manager)

2. Device Name
   Trade Name: **Master & Frank Surgical Drapes (Sterile)** i
   Common Name: Sterile Surgical Drapes
   Classification name: Drape , SURGICAL

3. Classification: Class II

4. Predicate Device: **Medline Disposable Surgical Drapes & Gowns ( K964142 )**

5. Device Description: **Master & Frank Surgical Drapes (Sterile),** is manufactured from non-woven fabric , PE & Reinforce layer. The Surgical Drapes includes (3) basic configurations of SPLIT DRAPE , THYROID SHEET and PEDIATRIC LAPAROTOMY DRAPE. The Surgical Drapes is supplied sterile and for single use only.

6. Intended Use: **Master & Frank Surgical Drapes (Sterile)** is a single use article intended to be used as a protective patient covering, such as to isolate a site of surgical incision for microbial and other contamination..

7. Performance Summary: In terms of Physical specification -- ASTM D1424 , ASTM D5034 & NFPA Flammability standards----etc, Biological specification ISO 10993 series & Sterilization Specification ISO 11137 & ISO 11607-1 , the device are designed to meet applicable standards..

8. Conclusions:

The **Master & Frank Surgical Drapes (Sterile)** have the same intended use and similar technological characteristics as the **Medline Disposable Surgical Drapes & Gowns ( K964142 ).** Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **Master & Frank Surgical Drapes (Sterile)** is substantially equivalent to the predicate devices.

510 (k) NUMBER (IF KNOWN): K020393

DEVICE NAME: **Master & Frank Surgical Drapes (Sterile)**

INDICATIONS FOR USE:

**Master & Frank Surgical Drapes (Sterile)** is a single use article intended to be used as a protective patient covering, such as to isolate a site of surgical incision for microbial and other contamination..

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020393

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-The-Counter X
(Per 21 CFR 801.109)